UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

OSSIFI-MAB LLC, **Plaintiff,** **v.** **AMGEN INC.,** **Defendant.**	**Case No. 23-cv-10861-DJC**

MEMORANDUM AND ORDER

CASPER, J. **June 21, 2024**

I. Introduction

Plaintiff OssiFi-Mab LLC ("OMAB") alleges that Defendant Amgen Inc. ("Amgen") has infringed certain claims of United States Patent Nos. 8,178,099 ("'099 patent"), 8,877,196 ("'196 patent"), 11,608,373 ("'373 patent") and 11,807,681 ("'681 patent") (collectively, the "Patents-in-Suit"). D. 73. The parties have agreed as to the construction of eleven claims, but now seek construction of three terms: one disputed term in the '373 patent and the '681 patent's claims and two disputed terms in the '196 patent, the '373 patent and the '681 patent's claims.[1] D. 69 at 1; D. 69-1 at 2–6. After reviewing the parties' claim construction briefs, D. 78; D. 81; D. 87; D. 89, and conducting a Markman hearing, D. 96, 97, the Court construes the disputed terms as follows.

[1] The Court adopts the parties' agreed constructions, as set forth in their joint statement. D. 69-1 at 4–6.

II. Patents-in-Suit

This lawsuit involves four of OMAB's patents related to methods of treating osteoporosis patients with a combination of two classes of drugs: sclerostin antagonists, which help stimulate bone growth, and anti-resorptive drugs, which slow the resorption of bone mass. D. 79-1; D. 79-2; D. 79-3; D. 79-4. The '099 patent was filed on December 21, 2007 and issued on May 15, 2012. D. 79-1 at 2. The '196 patent was filed on March 12, 2013 and issued on November 4, 2014. D. 79-2 at 2. The '373 patent was filed on September 19, 2016 and issued on March 21, 2023. D. 79-3 at 2. The '681 patent was filed on March 20, 2023 and issued on November 7, 2023. D. 79-4 at 2. The disputed terms concern claims in the '196, '373 and '681 patents. See D. 69-1 at 2–3.

III. Procedural History

OMAB instituted this action on April 21, 2023, D. 1, and amended the complaint on January 4, 2024. D. 73. Amgen has asserted counterclaims against OMAB, seeking a declaration of non-infringement and invalidity as to the Patents-in-Suit. D. 76. After claim construction briefing, the Court held a Markman hearing and took the matter under advisement. D. 96, 97.

IV. Standard of Review

The construction of disputed claim terms is a question of law. Markman v. Westview Instruments, Inc., 517 U.S. 370, 384 (1996). For claim construction, a court must construe "the meaning that the term would have to a person of ordinary skill in the art in question at the time of . . . the effective filing date of the patent application." Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). To do so, the Court must look to "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Id. at 1314 (quoting

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

A. The Claims

The analysis must begin with the language of the claim, which "define[s] the invention to which the patentee is entitled the right to exclude." Id. at 1312 (quoting Innova, 381 F.3d at 1115). "[T]he context in which a term is used in the asserted claim can be highly instructive." Id. at 1314. Courts may find that the claim itself provides the means for construing the term where, for example, the claim term is used consistently throughout the patent. Id. In that case, "the meaning of a term in one claim is likely the meaning of that same term in another." Abbott GmbH & Co., KG v. Centocor Ortho Biotech, Inc., No. 09-11340-FDS, 2011 WL 948403, at *3 (D. Mass. Mar. 15, 2011) (citing Phillips, 415 F.3d at 1314). Furthermore, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips, 415 F.3d at 1315.

B. The Specification

Nevertheless, the claims "do not stand alone" but "are part of a fully integrated written instrument, consisting principally of a specification," which "is always highly relevant to the claim construction analysis." Id. at *3 (internal quotation marks and citation omitted). "Usually, [the specification] is dispositive; it is the single best guide to the meaning of a disputed term." Id. (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "[T]he scope and outer boundary of claims is set by the patentee's description of his invention" and, therefore, "claims cannot be of broader scope than the invention that is set forth in the specification." On Demand Mach. Corp. v. Ingram Indus., Inc., 442 F.3d 1331, 1338–40 (Fed. Cir. 2006); see Phillips, 415 F.3d at 1315–17, 1323. The Court must "us[e] the specification [only] to interpret the meaning

of a claim," and must be careful not to "import[ ] limitations from the specification into the claim." Phillips, 415 F.3d at 1323. This standard may "be a difficult one to apply in practice," id., but "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." Id. at 1316 (citing Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

C. The Prosecution History

After the claims themselves and the specification, "a court should also consider the patent's prosecution history, if it is in evidence." Id. at 1317 (internal quotation marks omitted) (quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 980 (Fed. Cir. 1995)). "Like the specification, the prosecution history provides evidence of how the [United States Patent and Trademark Office] and the inventor understood the patent" and "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Id. (citing Vitronics, 90 F.3d at 1582–83). The prosecution history should be given less weight than the claims and the specification, however, because "it often lacks [ ] clarity . . . and thus is less useful for claim construction purposes." Id.

D. Extrinsic Evidence

Courts may also consider extrinsic sources, which "can help educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand claim terms to mean." Id. at 1319. In particular, "dictionaries and treatises can be useful in claim construction" as they may assist the court in understanding the underlying technology and "can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention." Id. at 1318. "[W]hile extrinsic evidence can shed useful light

on the relevant art," however, "it is less significant than the intrinsic record in determining the legally operative meaning of claim language." Id. at 1317 (internal quotation marks and citations omitted). In general, extrinsic evidence is viewed "as less reliable than the patent and its prosecution history in determining how to read claim terms." Id. at 1318. Extrinsic evidence, therefore, is "unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." Id. at 1319.

E. Indefiniteness

"Indefiniteness is a question of law which implicates underlying factual findings." Inline Plastics Corp. v. Lacerta Grp., Inc., 415 F. Supp. 3d 243, 248 (D. Mass. 2019) (citing Green Edge Enters., LLC v. Rubber Mulch Etc., LLC, 620 F.3d 1287, 1299 (Fed. Cir. 2010)). A patent claim is invalid for indefiniteness if its claims, when read in light of the specification and the prosecution history, "fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 901 (2014). "The definiteness requirement must take into account the inherent limitations of language, but at the same time, the patent must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them." Fairfield Indus., Inc. v. Wireless Seismic, Inc., No. 4:14-CV-2972, 2015 WL 1034275, at *4 (S.D. Tex. Mar. 10, 2015) (quoting Nautilus, 572 U.S. at 909–10). Patents are presumed to be valid, 35 U.S.C. § 282, and indefiniteness must be proved by the more demanding standard of clear and convincing evidence. Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 95 (2011).

V. Construction of Disputed Claims

The parties dispute the meaning of the following three terms and the Court resolves these disputes as discussed below:

A. "Being Treated With"

Term	OMAB's Proposed Construction	Amgen's Proposed Construction
being treated with a humanized sclerostin-recognizing antibody ('373 patent, claims 1, 3, 9, 11, 15, 24)	at the time the method is beginning, having been undergoing treatment with a humanized sclerostin-recognizing antibody	during the course of a humanized sclerostin-recognizing antibody treatment
being treated with a sclerostin-recognizing antibody ('681 patent, claims 1, 24, 29)	at the time the method is beginning, having been undergoing treatment with a sclerostin-recognizing antibody	during the course of a sclerostin-recognizing antibody treatment
being treated with a humanized sclerostin-recognizing antibody and vitamin D ('681 patent, claim 27)	at the time the method is beginning, having been undergoing treatment with a humanized sclerostin-recognizing antibody and vitamin D	during the course of treatment with both a humanized sclerostin-recognizing antibody and vitamin D

D. 69-1 at 2. The term "being treated with" appears in the preambles of claims in the '373 and '681 patents. D. 79-3 at 23–24; D. 79-4 at 19–20. These claims are directed to methods of medical treatment that involve the use of antiresorptive drugs to treat bone disorders in patients "being treated with" a sclerostin-recognizing antibody. Id. Claim 1 of the '373 patent is illustrative of how the term is used in these claims: "A method for promoting bone growth in a human subject being treated with a humanized sclerostin-recognizing antibody, comprising administering an antiresorptive drug to the subject." D. 79-3 at 23.

OMAB urges the Court to construe the term "being treated with" as "at the time the method is beginning, having been undergoing treatment with." D. 78 at 10. OMAB asserts that this construction reflects the plain meaning of the phrase in light of the structure and context of the

claims, id. at 10–12, and also points to the description of the invention in the specification and the prosecution history of the patents to support its construction. Id. at 12–15. Amgen argues that the literal, plain-English meaning of "being treated with" is that the antiresorptive drug is administered "during the course of a treatment" with a sclerostin-recognizing antibody, D. 81 at 10–11, and also contends that the specification and the prosecution history of the claims support its proposed construction. Id. at 13–16.

The parties agree that "claim[s] must be read in accordance with the precepts of English grammar." In re Hyatt, 708 F.2d 712, 714 (Fed. Cir. 1983); see D. 81 at 11; D. 87 at 7 n.1. They disagree, however, over whether OMAB's proposed construction is grammatically sound. D. 81 at 11–12; D. 87 at 6–8. The term "being treated with" uses the verb "to be" in the present participle, thus indicating the existence of some present condition. According to Amgen, the condition that must be present for the method to apply, e.g., for an antiresorptive drug to be administered, is a "course of treatment" with a sclerostin-recognizing antibody. D. 81 at 11–12. OMAB denies that its proposed construction, "at the time the method is beginning, having been undergoing treatment with," is inconsistent with the precepts of English grammar. D. 87 at 6–8. OMAB acknowledges that the use of "to be" in the present participle indicates that treatment with a sclerostin-recognizing antibody must be occurring in the present but maintains that the term, as used in the preambles, "specifies the state of the patient when the method begins, i.e., in the present moment at the start of the method." D. 87 at 6. According to OMAB, "being treated with" allows a person of ordinary skill in the art to identify which patients possess a present condition (i.e., being treated with a sclerostin-recognizing antibody) that would make them eligible for the method. Id. at 6–7.

The context of the disputed term lends some support to OMAB's general position, if not its exact construction. As noted above, "being treated with" appears in the preambles of the claims;

preambles reflect "statements of the intentional purpose for which the methods must be performed." Eli Lilly & Co. v. Teva Pharms. Int'l GmbH, 8 F.4th 1331, 1342 (Fed. Cir. 2021). Accordingly, "being treated with" is more probative of the conditions present at the outset of the method—e.g., the patients eligible for the method—than the specific "course" of treatment or other conditions that must exist throughout the entire duration of the method's application. This reading comports with how the term appears. For example, claim 15 of the '373 patent explains that the method is reserved for a "human subject with low bone mass being treated with a sclerostin-recognizing antibody." D. 79-3 at 24. If this language described the specific conditions that must exist throughout the application of the method, rather than the general characteristics of eligible patients, then a patient with "low bone mass" would be excluded from the method the moment said patient experiences bone mass improvements—an outcome which would appear to defeat the purpose of the claim.

The specification also provides that the "[sclerostin] antagonist may be coadministered or serially administered with an antiresorptive drug." D. 79-3 at 15. This description indicates that the patented method, as applied, extends not only to patients as they are presently receiving antibody treatment but also to patients who may have recently completed a course of treatment. Similarly, OMAB's construction comports with certain dependent claims. See Phillips, 415 F.3d at 1315. Claims 23 and 24 of the '373 patent, which depend on claim 15, require that the "antiresorptive drug is administered alone." This language would make little sense, however, if the antiresorptive drug must be coadministered at the same time a patient is receiving treatment with a sclerostin-recognizing antibody. See Littlefuse, Inc. v. Mersen USA EP Corp., 29 F.4th 1376, 1380 (Fed. Cir. 2022) (declining to adopt a construction that "would not merely render the dependent claims superfluous, but would mean that those claims would have no scope at all");

Ortho-McNeil Pharm. v. Mylan Lab'ys, Inc., 520 F.3d 1358, 1362 (Fed. Cir. 2008) (explaining that the "[t]his court strives to reach a claim construction that does not render claim language in dependent claims meaningless").

Although the context of the claims and the specification offer some support for OMAB's proposed construction, however, the temporal scope of the term "being" cannot stretch so far as to mean "at the time the method is beginning, having been undergoing treatment with." See Innova, 381 F.3d at 1116 (emphasizing that "a claim construction analysis must begin and remain centered on the claim language itself"). Such a construction would, as Amgen notes, change the tense of "being" to "having been," which is inconsistent with the plain language of the term. At the same time, the addition of the word "course" in Amgen's proposed construction would render the scope of the present condition (i.e., treatment with a sclerostin-recognizing antibody) too narrow and would exclude forms of treatment, such as the administration of a course of treatment with an antiresorptive drug followed by a course of treatment with a sclerostin-recognizing antibody, which the claims, according to their context and the specification, were meant to reach.

Accordingly, rather than adopt the proposed construction of either party, the Court construes the term "being treated with" to mean "during treatment with."[2] To situate this

[2] The Court has considered the parties' arguments as to prosecution history, D. 78 at 14–15; D. 81 at 14–16, but affords little weight to same in light of the plain meaning of the term, the context of the claims and the specification. See Phillips, 415 F.3d at 1317. Nonetheless, the prosecution history suggests that the applicant at least understood "being treated with" to describe the patients eligible for the method's application at its outset. According to the file history of the '373 patent, the Applicant added claim 98 on October 15, 2021 (which issued as claim 1 of the '373 patent); claim 98 referred to a "method for promoting bone growth in a human subject being treated with a humanized sclerostin-recognizing antibody, comprising administering an antiresorptive drug to the subject." D. 79-5 at 5. The applicant noted that the claim was directed to "a particular human subject having a particular state." Id. at 8. The examiner interviewed the applicant and then, in summarizing the interview, noted that claim 98 "does not recite administration of an antibody" but instead "define[s]" the "patient population" as "having been treated with an antibody." D. 79-6 at 3.

construction in the claims in which the term arises, the Court construes the disputed term as follows: (1) "being treated with a humanized sclerostin-recognizing antibody" means "during humanized sclerostin-recognizing antibody treatment"; (2) "being treated with a sclerostin-recognizing antibody" means "during sclerostin-recognizing antibody treatment"; and (3) "being treated with a humanized sclerostin-recognizing antibody and vitamin D" means "during treatment with a humanized sclerostin-recognizing antibody and vitamin D."

B. "Administering . . . Sequentially With" and "Serially Administered"

The term "administering . . . sequentially with" appears in claim 1 of the '196 patent and refers to a "method of increasing bone density in a mammalian patient in need thereof." D. 79-2 at 17. This method entails "systematically administering to a said mammalian patient a therapeutic comprising an effective amount of Sclerostin antagonist sequentially with an antiresorptive drug." Id. The term "serially administered" is used in a substantively identical manner in claims of the '373 and '681 patents, and the parties raise the same arguments as to both terms. D. 79-3 at 24; D. 79-4 at 19–20. Accordingly, the Court analyzes the disputed terms together. See Baran v. Med. Device Techs., Inc., 616 F.3d 1309, 1316 (Fed. Cir. 2010) (noting that the terms "releasably" and "detachable" had the same meaning where the patentee "used the two terms interchangeably").

Term	**OMAB's Proposed Construction**	**Amgen's Proposed Construction**
administering . . . sequentially with ('196 patent, claim 1)	administered such that administration of one drug follows completion of the course of treatment with the other drug	Indefinite
serially administered ('373 patent, claim 14) ('681 patent, claim 12)	administered such that administration of the antiresorptive drug follows completion of the course of	Indefinite

	treatment with the sclerostin-recognizing antibody	
serially administering ('373 patent, claim 15) ('681 patent, claim 29)	administering such that administration of the antiresorptive drug follows completion of the course of treatment with the sclerostin-recognizing antibody	
administered serially ('681 patent, claim 28)	administered such that administration of the alendronate follows completion of the course of treatment with the sclerostin-recognizing antibody	

D. 69-1 at 2-3. OMAB urges the Court to construe the terms "administer[ed] . . . sequentially with" and "serially administered" to each mean "administered such that administration of one drug follows completion of the course of treatment with the other drug." D. 78 at 16–19. Amgen contends that these terms are indefinite because they do not identify when specifically the administration of one drug must follow the other or otherwise set the outer bounds of the claimed use and, accordingly, the claims which include the terms are invalid. D. 81 at 17–24.

OMAB's proposed construction is consistent with how the terms are used in the patents abstracts and the claims. The abstract of the '196 patent is illustrative, providing that "the Sost antagonist may be coadministered together or sequentially with a matrix conducive to anchoring new bone growth." D. 79-2 at 2. The parties agree that "together" means the administration of one drug "during the course of treatment" with the other. See D. 69-1 at 6. Thus, "sequentially" or "serially" at least mean that the administration of the antiresorptive drug does not occur while a course of treatment with the sclerostin-recognizing antibody is ongoing. There is also evidence from the prosecution history that, in the context of drug administration, the applicant and the

examiner understood "sequentially" as distinguishable from "concurrently." See D. 79-8 at 13–14 (noting by examiner that drugs may be coadministered "either concurrently or sequentially"); D. 79-9 at 10 (distinguishing by applicant between "sequentially" and "together"). The Court also notes that medical studies, proffered by OMAB, similarly support its proposed construction. See, e.g., D. 79-10 at 9; see also Phillips, 415 F.3d at 1319 (explaining that extrinsic sources "can help educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand claim terms to mean").

Amgen maintains that the terms "administer[ed] . . . sequentially with" and "serially administered" are indefinite because "a person of ordinary skill in the art would have no way to know how close together or far part the two medications need to be administered." D. 81 at 17. Terms within a patent do not need to be defined with "mathematical precision," however, as long as there exist "objective boundaries" to inform a person of ordinary skill in the art about the scope of the invention with "reasonable certainty." See Guangdong Alison Hi-Tech Co. v. Int'l Trade Comm'n, 936 F.3d 1353, 1359–60 (Fed. Cir. 2019).

To that end, OMAB has proffered the declaration of Dr. Anthony Sebba, a rheumatologist who attests to having "knowledge of key scientific and clinical concepts in the field of osteoporosis." D. 80 ¶¶ 1, 5–6, 13. Dr. Sebba states that "sequential" administration "is used in the scientific literature not only as a clear alternative to co-administration, but also specifically referring to treatment in which administration of one drug follows completion of the course of treatment with another drug." Id. ¶ 107. Dr. Sebba emphasizes that "[t]he key here is that administration of the second drug **follows** the first, such that administration of the two drugs are part of a larger treatment regimen with a common therapeutic objective," and opines that a person of ordinary skill in the art would be reasonably certain of same. Id. ¶ 109 (emphasis in original).

Thus, the existence of a larger treatment regimen with a common therapeutic objective sets an objective boundary for the terms' meaning, see Guangdong, 936 F.3d at 1360, and Amgen has not adduced clear and convincing evidence to the contrary. Accordingly, the Court adopts OMAB's proposed construction but revises it to add the following language, "as part of a larger treatment regimen with a common therapeutic objective."

VI. Conclusion

For the foregoing reasons, the disputed claim terms are construed as follows:

1. The term "being treated with" means "during treatment with."
2. The term "administering . . . sequentially with" means "administering such that administration of one drug follows completion of the course of treatment with the other drug as part of a larger treatment regimen with a common therapeutic objective."
3. The term "serially administered" means "administered such that administration of one drug follows completion of the course of treatment with the other drug as part of a larger treatment regimen with a common therapeutic objective."

So Ordered.

/s Denise J. Casper
United States District Judge